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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/025,635 | 02/18/1998 | SHENG-ZHI PANG | 19603/1552(1) | 9815 |
| 7590 | 12/03/2003 | | | EXAMINER |
| MICHAEL L GOLDMAN NIXON PEABODY LLP CLINTON SQUARE P O BOX 1051 ROCHESTER, NY 14603 | | | KUBELIK, ANNE R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1638 | |
| DATE MAILED: 12/03/2003 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/025,635 | PANG ET AL. | |
| | Examiner | Art Unit | |
| | Anne R. Kubelik | 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 June 2003 and 11 August 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) See Continuation Sheet is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-5,9-12,16-20,23-25,27-29,31-36,40-43,46-50,53-62,66-74,77-81 and 95-103 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 18 February 1998 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-5,9-12,16-20,23-25,27-29,31-36,40-43,46-50,53-62,66-74,77-81 and 95-103.

DETAILED ACTION

1. The request filed on 27 May 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/025,635 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 66-74, 77-81 and 95-103 are pending.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The Declaration of Dennis Gonsalves, filed 4 June 2003, in response to an enablement rejection, has been considered.
5. The rejection of claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 66-74, 77-81 and 93-94 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA constructs comprising a trait DNA molecule from the tomato spotted wilt virus and silencer DNA molecules that are the green fluorescent protein and the turnip mosaic potyvirus coat protein genes, a method of using them to impart the trait of resistance to turnip mosaic potyvirus and tomato spotted wilt virus to a plant, and plants so transformed, does not reasonably provide enablement for DNA constructs comprising any trait DNA and any silencer DNA and methods of using them to impart any trait is withdrawn in light of Applicant's amendments to the claims to recite minimum length of the trait [first] and silencer [second] DNAs as having minimum lengths of 110 and 400 nucleotides respectively.
6. The rejection of claims 1-5, 9-12, 16-17, 19-20, 23-25, 27-29, 31-36, 40-41, 43, 46-50, 53-54 and 56-57 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lawson et al (1990 Bio/Technol. 8:127-134) is withdrawn in light of Applicant's amendments to recite

minimum length of the trait [first] and silencer [second] DNAs as having minimum lengths of 110 and 400 nucleotides respectively and in light of Applicant's arguments filed 4 June 2003 that the coat protein genes of Lawson et al are under separate promoters.

7. The rejection of claims 1-4, 9-11, 16-17, 19-20, 23-25, 27-29, 31-35, 40-41, 43, 46-49, 53-61, 66-67, 69-74, 77-78, 80-81 and 93-94 remain rejected under 35 U.S.C. 102(a) as being anticipated by Tricoli et al (WO 96/21031) is withdrawn in light of Applicant's amendments to recite minimum length of the trait [first] and silencer [second] DNAs as having minimum lengths of 110 and 400 nucleotides respectively and in light of Applicant's arguments filed 4 June 2003 that the coat protein genes of Tricoli et al are under separate promoters.

8. The rejection of claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 66-74, 77-81 and 93-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tricoli et al (WO 96/21031) is withdrawn in light of Applicant's amendments to recite minimum length of the trait [first] and silencer [second] DNAs as having minimum lengths of 110 and 400 nucleotides respectively and in light of Applicant's arguments filed 4 June 2003 that the coat protein genes of Tricoli et al are under separate promoters.

Claim Objections

9. Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. First DNA molecules are defined in parent claim 1 as being of a length insufficient to impart a trait. Thus, claim 19, which states that one of a plurality of first

DNA molecules has a length that is long enough to impart a trait, is broader than the claim upon which it depends.

10. Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The construct of claim 1 already effects post-transcriptional gene silencing of the first DNA molecule. Thus, claim 20 fails to further limit claim 1.

11. Claim 100 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The construct of parent claim 95 only imparts a single trait to plants, while in claim 100 recites that plants transformed with the construct have more than one trait. Thus, claim 100 is broader than the claim upon which it depends.

Claim Rejections - 35 USC § 112

12. Claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 66-74, 77-81 and 95-103 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 26 December 2002, as applied to claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 66-74, 77-81 and 93-94. Applicant's arguments filed 4 June 2003 and 11 August 2003 have been fully considered but they are not persuasive.

The claims are broadly drawn to a multitude of DNA constructs comprising viral DNAs that are insufficient in length to impart a trait, wherein the viral DNAs can include those encoding a coat protein, those encoding a replicase, those not encoding a protein, those encoding a viral gene product and combinations thereof, and comprising second DNAs. In contrast, the specification only describes a trait DNA molecule from the tomato spotted wilt virus and silencer DNA molecules that are the green fluorescent protein and the turnip mosaic potyvirus coat protein genes. Applicant does not describe other DNA molecules encompassed by the claims, including viral DNAs that are insufficient in length to impart a trait, viral DNAs encoding a coat protein, viral DNAs encoding a replicase, viral DNAs not encoding a protein, viral DNAs encoding a viral gene product, combinations thereof, and second DNAs. The structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

Furthermore, Applicant does not describe plants having the myriad of potential traits as broadly claimed.

Hence, Applicant has not, in fact, described first and second DNAs within the full scope of the claims and plants with the imparted traits, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

Applicant urges that the limitations describing the trait [first] DNA as being insufficient to independently impart a trait to plants and the silencer [second] DNA as being effective to achieve post-transcriptional silencing of the trait DNA demonstrate that Applicant's were in possession of the claimed invention (4 June 2003 response pg 4).

This is not found persuasive because viral DNAs that are insufficient in length to impart a trait, viral DNAs encoding a coat protein, viral DNAs encoding a replicase, viral DNAs not encoding a protein, viral DNAs encoding a viral gene product, combinations thereof, and second DNAs are not described within the full scope of the claims.

13. Claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 66-74, 77-81 and 95-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is modified from the rejection set forth in the Office action mailed 26 December 2002, as applied to claims 1-5, 9-12, 16-20, 23-25, 27-29, 31-36, 40-43, 46-50, 53-62, 70-74, 77-81 and 93-94. Applicant's arguments filed 4 June 2003 and 11 August 2003 do not apply to these new rejections.

Claim 1 is indefinite of its recitation of "fragment of a first DNA molecule which has a length insufficient to independently impart a trait". It is unclear if it is the fragment or the first DNA molecule that has a length insufficient to impart the trait. Claim 95 is similarly indefinite in its recitation of "fragments of DNA molecules ... which ... have a length insufficient to independently impart a trait".

It is unclear in claims 2, 24, 28, 33, 47, 59 and 71 if the plurality of different first DNA molecules are fragments from the same gene or if all the first DNA molecules are heterologous to one another. It is also unclear if the plurality of different first DNA molecules together impart a single trait to plants or if they each impart different traits to plants.

Claim 46 is indefinite in its recitation of "conditions effective to impart a trait". It is unclear what those conditions are.

Unless claim 57 has a step in which progeny comprising the construct are selected, the method will be broader than the method of claim 47, upon which the claim depends, because not all progeny will inherit the DNA construct.

Claim 57 and 81 lack antecedent basis for the limitation "the plants transformed with said DNA construct" in line 3.

It is unclear in claim 95 if the plurality of DNA molecules are fragments from the same gene or if all the DNA molecules are heterologous to one another. Because they impart a single trait to plants, it suggests that they are not heterologous to one another and are all from the same gene.

14. On 26 November 2003, Applicant was sent proposed claim amendments that would have addressed the rejections made herein and would have made the claims allowable. Applicant's representative did not approve the claim amendments.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm. Sometime in January 2004, the examiner's phone number will change to 571-272-0801.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
December 1, 2003



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